

Application No. 10/609,120  
Attorney Docket No. 11187-00016

(Endow-3)

Reply to Office Action of May 11, 2005

### REMARKS

In the Office Action under reply, claims 1-32 have been examined. The Examiner has rejected claims 1, 3, and 6-32 under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement and has maintained the following art-based rejections:

1. Under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,886,024 to Vallee et al. (claims 1-32);
2. Under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,679,806 to Zheng et al. (claims 1-3, 6-13, 16-23, 26-28, 31, and 32);
3. Under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,783,189 to Pei et al. (claims 1-3, 6-13, 16-23, 26-28, 31, and 32);
4. Under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 4,960,908 to Ito et al. (claims 26-28, 31, and 32);
5. Under 35 U.S.C. §102(b) as anticipated by French Patent No. FR 2190411 to Blaise et al. (claims 126-28 and 31-32); and
6. Under 35 U.S.C. §102(b) as anticipated by Jagdish et al. (claims 26, 27, 29, and 30-32).

As no additional amendments have been made herein, claims 1-32 remain pending in the application. The Examiner's rejections are fully traversed by the arguments presented below.

### **THE JUNE 30, 2005, TELEPHONE INTERVIEW**

Applicants wish to thank Examiner Trinh for his time in extending a telephone interview to the undersigned attorney on June 30, 2005. During the interview, the specifics of the rejection under 35 U.S.C. §112, first paragraph, were discussed. The Examiner clarified that the rejection was in two parts, the first being based on the proviso language added to claims 1, 7, 17, and 26 in the previous response filed on February 4, 2005, and the second being a reiteration of the rejection based on a presumed failure to recite a known or recognized disease.

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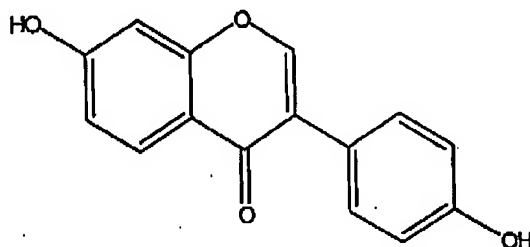
### THE REJECTIONS UNDER 35 U.S.C. §112, FIRST PARAGRAPH

The Examiner has rejected claims 1, 3, and 6-32 for failing to comply with the written description requirement. In the telephone interview on June 30, 2005, the Examiner clarified that the rejection was in two parts, the first being based on the proviso language added to claims 1, 7, 17, and 26 in the previous response filed on February 4, 2005, and the second being a reiteration of the rejection based on a presumed failure to provide a known or recognized disease. Applicants disagree with both aspects of the rejection as discussed separately below.

#### The Proviso-Based Aspect

The Examiner has asserted that the proviso language added to claims 1, 7, 17, and 26 raises the issue of new matter as, according to the Examiner, the specification fails to provide teaching and/or working examples that support the newly incorporated language.

In response to the Examiner's contention, Applicants submit that the Examiner has failed to appreciate the fact that the proviso language only serves to exclude a specific compound, daidzin, from the scope of the claims. The proviso in question states that  $R_5$  cannot be hydroxy when  $R_1$ ,  $R_2$ ,  $R_3$ ,  $R_4$ ,  $R_6$ , and  $R_7$  are all hydrogen. When  $R_1$ ,  $R_2$ ,  $R_3$ ,  $R_4$ ,  $R_6$ , and  $R_7$  are all hydrogen and  $R_5$  is hydroxy, the resulting compound of Formula I has the following structure:



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which the Examiner will agree is clearly daidzein. As daidzein was identified in the specification as compound 40 in the table on page 17 of the specification, it may be expressly excluded from the application. Applicants refer the Examiner to section 2173.05(i) of the MPEP. As stated in the third paragraph of this section, "[i]f alternative elements are positively recited in the specification, they may be explicitly excluded in the claims."

### **The Lack of a Known or Recognized Disease Aspect**

In his previous rejection, The Examiner asserted that claims 1-6 fail to distinctly claim the subject matter that Applicant regards as the invention as the language "inhibiting ALDH-2" does not stand for a specific or meaningful disease. Similarly, claims 17-24 were rejected for their inclusion of the language "identifying a compound that modulates ALDH-2." In the present Office Action, the Examiner has not included claims 2, 4, and 5, in the rejection under 35 U.S.C. §112, first paragraph, and so Applicant's assume that the rejection as it pertains to claims drawn to methods of inhibiting ALDH-2 has been withdrawn. If this assumption is in error, Applicants request that the Examiner further clarify exactly which claims are rejected for which reasons.

Presumably, claims 17-25, drawn to methods of identifying a compound that modulates ALDH-2 stand rejected. Applicants have included claim 25 in this rejection as it depends from rejected independent claim 18 and it is possible that the Examiner inadvertently omitted the claim in the rejection.

The Examiner has supported the rejection by stating that the identification of a compound that modulates ALDH-2 is not a specific or meaningful disease. Applicants submit that there is no requirement that a claim must be drawn to a method of treating a specific disease or condition in order to satisfy the requirements of 35 U.S.C. §112, first paragraph. Numerous patents include claims drawn to methods of identifying compounds that modulate the activity of a specific enzyme. This is a common type of research-tool claim that is clearly understood to be fully patentable under common practice.

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Forth these reasons, Applicants submit that the pending claims fully satisfy the requirements of 35 U.S.C. §112, first paragraph. The rejection is in error and its withdrawal is requested.

#### THE REJECTIONS UNDER 35 U.S.C. §102(B)

The Examiner has maintained the previous art based rejections without considering the arguments presented in the response filed February 4, 2005. The Examiner concluded that Applicants' remarks were moot in view of the new rejection under 35 U.S.C. §112, first paragraph.

As discussed above, the proviso language added to independent claims 1, 7, 17, and 26, does not raise any issues of new matter and therefore the rejection under 35 U.S.C. §112, first paragraph, is in error and should be withdrawn. Applicants ask that the Examiner now kindly consider the arguments presented in the February 4 response against each of the rejections under 35 U.S.C. §102(b). For the Examiner's convenience those arguments are restated here below:

#### VALLEE ET AL.

The Examiner has rejected claims 1-32 over the disclosure in the Abstract and column 15 of Vallee et al. asserting that the compounds depicted therein anticipate the presently claimed invention. Applicants respectfully disagree.

Each of the compounds described in Vallee et al. possess and a hydroxy group in the R<sub>5</sub> position of the presently pending claims as well as an alkyl, hydroxyalkyl, or carboxyalkyl group in the R<sub>1</sub> position. That is, the Vallee et al. compounds contain both R<sub>5</sub> hydroxy moieties and R<sub>1</sub> alkyl, hydroxyalkyl, or carboxyalkyl moieties. In contrast, compounds having both R<sub>5</sub> hydroxy moieties and R<sub>1</sub> alkyl, hydroxyalkyl, or carboxyalkyl moieties are excluded from the scope of the presently pending claims.

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As the Examiner will see, the currently pending claims require one of two versions of the compounds of the invention. The first of these two versions, version A, is recited in claims 1, 3, 6, 7, 9-13, 16, 17, 19-23, 26, 28, 31, and 32, while the second version, version B, is recited in claims 2, 4, 5, 8, 14, 15, 18, 24, 25, 27, 29, and 30.

Version A and version B differ in the following two ways:

1. Version A claims allow hydroxy substituents in the  $R_5$  position, while version B claims do not.
2. Version B claims allow alkyl, hydroxyalkyl, or carboxyalkyl moieties substituents in the  $R_1$  position, while version A claims do not.

Thus, there are no pending claims in the present application that include compounds having both  $R_5$  OH moieties and  $R_1$  alkyl, hydroxyalkyl, or carboxyalkyl moieties. Given that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987), it is clear that the compounds disclosed in Vallee et al., do not anticipate the subject matter of the presently pending claims. The rejection is in error and its reconsideration and withdrawal are in order and are respectfully requested.

#### ZHENG ET AL.

The Examiner has rejected claims 1-3, 6-13, 16-23, 26-28, 31, and 32 over the disclosure of the compounds of Fig. 1 in Zheng et al. asserting that the compounds depicted therein anticipate the presently claimed invention. Applicants respectfully disagree.

Zheng et al. disclose some of the previously known analogs of daidzin. Applicants point out that each of the disclosed analogs contains a hydroxy group at the  $R_5$  position and either:

1. a heterocyclic group at the  $R_1$  position, i.e., daidzin, genistin, 6"-O-acetyl daidzin, 6"-O-acetyl genistin, 6"-O-malonyl daidzin, and 6"-O-malonyl genistin,

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2. a heterocyclic group at the R<sub>2</sub> position, i.e., puerarin, or
3. an alkoxy group at the R<sub>7</sub> position, i.e. glycitein.

As discussed above, the B version of the presently pending claims does not allow for hydroxy at the R<sub>5</sub> position. Given the presence of an R<sub>5</sub> hydroxyl in each Zheng et al. compound, claims 2, 8, 18, and 27 cannot be anticipated by the disclosure in Zheng et al.

With respect to the remaining rejected claims, i.e., claims 3, 6, 7, 9-13, 16, 17, 19-23, 26, 28, 31, and 32, Applicants wish to point out that, independent claims 1, 7, 17, and 26 include neither R<sub>1</sub> heterocyclic groups nor R<sub>7</sub> alkoxy groups. Furthermore, none of the claims have ever included R<sub>2</sub> heterocyclic groups.

Given that the compounds disclosed in Zheng et al. do not fall within the scope of the pending claims, they do not provide a basis for a rejection under 35 U.S.C. §102(b). Reconsideration and withdrawal of the rejection over Zheng et al. is accordingly requested.

#### PEI ET AL.

The Examiner has rejected claims 1-3, 6-13, 16-23, 26-28, 31, and 32 over the disclosure of the compounds NPI-031D and NPI-031E in the reference, asserting that these compounds anticipate the presently claimed invention. Applicants respectfully disagree.

As discussed above, independent claims 2, 8, 18, and 27 do not allow for the R<sub>5</sub> hydroxyl group required by NPI-031D and NPI-031E. Clearly, these claims and all claims dependent thereupon are not anticipated by Pei et al.

With respect to currently pending independent claims 1, 7, 17, and 26, as amended these claims do not allow for heterocyclic groups in the R<sub>1</sub> position as required by NPI-031D. Also, independent claims 1, 7, 17, and 26 now contain proviso language specifically stating that R<sub>5</sub> cannot be -OH when R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub>, R<sub>4</sub>, R<sub>6</sub>, and R<sub>7</sub> are all H, thereby excluding NPI-031E.

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For these reasons, Pei et al. does not anticipate rejected independent claims 1, 2, 7, 8, 17, 18, 26, and 27 or any other claims dependent thereupon. Reconsideration and withdrawal of the rejection are in order and are respectfully requested.

#### ITO ET AL.

The Examiner has rejected claims 26-28, 31, and 32 over the disclosure presented in the Abstract and in the material spanning line 54 of column 1 to line 28 of column 2 of Ito et al. The Examiner contends that the compounds depicted in these sections anticipate the presently claimed invention. Applicants respectfully disagree.

Ito et al. discloses a group of isoflavone derivatives having various amino, amido, thio, or carboxy moieties in the R<sub>3</sub> position of the currently claimed compounds. As amended, independent claims 26 and 27 specify that R<sub>3</sub> must be hydrogen. Given that the compounds of the invention cannot contain the various R<sub>3</sub> amino, amido, thio, or carboxy moieties of Ito et al., the reference cannot anticipate the subject matter of claims 26 and 27 or any claims dependent thereupon. Reconsideration and withdrawal of the rejection are in order and are accordingly requested.

#### BLAISE ET AL.

The Examiner has rejected claims 26-28, 31, and 32 over the compounds of Formula I and II, as presented on page 1 of the reference. The Examiner contends that these compounds anticipate the presently claimed invention. Applicants respectfully disagree.

The compounds disclosed by Blaise et al. contain C<sub>1-3</sub> alkoxy-carbonylalkyl moieties in the R<sub>1</sub> position. These moieties are not within the scope of the presently pending claims. Independent claim 26 does not allow any alkoxy-carbonylalkyl groups in the R<sub>1</sub> position and independent claim 27 permits only C<sub>4-6</sub> alkoxy-carbonylalkyl groups. The compounds disclosed by Blaise et

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al. do not fall within the scope of the independent claims and do not anticipate the independent claims or any claims dependent thereupon. Withdrawal of the rejection is requested.

**JAGDISH ET AL.**

The Examiner has rejected claims 26, 27, 29, 31, and 32 over the 24 compounds presented on pages 1097-1098 of the reference. The Examiner contends that these compounds anticipate the presently claimed invention. Applicants respectfully disagree.

Applicants submit that none of the 24 compounds disclosed in the reference fall within the scope of the pending claims for one or more reasons. This can be demonstrated as follows:

1. Compounds 1, 4, 5, 7, 19, 20, and 22 all fail to contain an oxygen atom adjacent to the R<sub>1</sub> position.
2. Compounds 3, 6, 7, 9, 10, 12-17, 20, 22, and 23 all contain substituents other than hydrogen at the R<sub>3</sub> position. As discussed above, independent claims 26 and 27 now require that R<sub>3</sub> be hydrogen, as do all claims dependent thereupon.
3. Claims 3, 5-11, 13, 14, 16-18, and 24 fail to anticipate the pending claims as all of these claims have alkyl moieties in the R<sub>2</sub> position, a substitution that is not allowed in either of the independent claims.
4. Claims 2, 3, 6, 7, 14, 18, and 21, also fail to anticipate the pending claims as they contain substituents other than hydrogen or hydroxide at the R<sub>6</sub> position.

As none of the cited compounds in the reference fall within the scope of the pending claims, the rejection is in error. Reconsideration and withdrawal of the rejection are in order and are requested.



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**CONCLUSION**

For the foregoing reasons, Applicant submits that the claims are in condition for allowance. A Notice of Allowance is requested, and a prompt mailing thereof would be much appreciated.

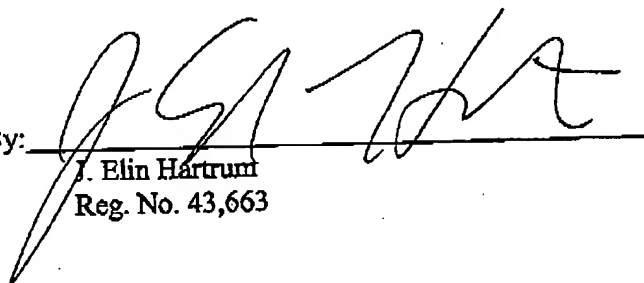
Should the Examiner have any questions, he is invited to contact the undersigned attorney at (650) 384-8755.

Respectfully submitted,

Date:

8/1/05

By:



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